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Unintended pregnancies (UIPs) and STDs with their sequelae of ectopic pregnancy continue to be epidemic among active duty enlisted women. Such reproductive health problems result in major morbidity among affected women as well as posing a potential threat to combat readiness. UIPs and STDs result from complex interactions between biological and behavioral factors. The ultimate control in preventing such morbidities must rely on both behavioral and biologic strategies. The primary aim of the project is to develop, implement, and evaluate an intervention which emphasizes correct information, motivation and behavioral skills building (IMB Model) coupled with non-invasive screening using urine-based amplified DNA techniques to detect *C. trachomatis* and *N. gonorrhoeae* and urine-based pregnancy testing. A randomized controlled trial design was employed to evaluate the impact of the intervention on the experimental group using both self-report questionnaires (psychosocial and behavioral risk factors) and results from the STD and pregnancy screening tests as measures. The control intervention consisted of a prevention program focusing on nutrition, breast cancer, fitness and injury prevention. Questionnaires and biologic testing were completed at baseline, 2-4 weeks, 9-12 months post intervention. Participants (N=2157) were women enrolled in recruit training for the U.S. Marine Corps.

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3. INTRODUCTION

Overall Goal: To prevent sexually transmitted diseases (STDs) and unplanned pregnancies (Focus curriculum) and to promote good nutritional habits and reduce sports/training injuries (Fitness-for-Life curriculum) through the provision of information, communication and problem-solving skills training, use of program-specific videos, and group discussions which emphasize prevention of risk behaviors and negative peer influences. The curricula for both components were implemented in 4, two-hour sessions that occur during Recruit Training (Parris Island, SC). Screening for pregnancy and prevalent STDs, including chlamydia, gonorrhea, and trichomonas is also included.

Participants: Junior, enlisted women Marine Recruits who voluntarily agreed to participate in the program were randomly assigned by platoons to either the Focus (Study condition) or Fitness-for-Life (Control condition) Curricula at arrival at recruit training.

Assessments: (*Completed*) All participants completed a self-report questionnaire of their knowledge, attitudes, beliefs, and behaviors regarding STDs, unplanned pregnancies, nutrition and fitness at T-1 baseline (prior to participation in the Program at Recruit Training Regiment-RTR, Parris Island, SC), at T-2 after completing Marine Combat Training (MCT at Camp LeJeune, NC, approximately 2-4 weeks from graduation from recruit training) which was preceded by boot leave, and at T-3 which is 9-12 months post-MCT at their first duty assignment or MOS School. These individuals were also screened for pregnancy and STDs at each of the three assessment periods.

Program Evaluation: (*Ongoing analyses, see publications and plans for manuscripts and analyses under preparation*) The primary goal of the program evaluation is to determine the feasibility and effectiveness of the Focus curriculum for preventing unplanned pregnancies and STDs and the Fitness-for-Life curriculum for promoting good nutritional habits and reducing sports/performance injuries in junior enlisted women Marines.

Specific Aims:

- (A) Develop, implement, and evaluate a reproductive health educational and cognitive-behavioral skills-building intervention (behavioral intervention) designed to modify knowledge, psychosocial and behavioral risk factors associated with UIPs and STD acquisition.
- (B) Test the relevance of the Information, Motivation, and Behavioral Skills (IMB) Model in explaining the determinants of behaviors linked with UIPs and STDs.
- (C) Define the prevalence of UIPs and STDs, emphasizing the most common bacterial agents, such as *C. trachomatis* and *N. gonorrhoeae*, and their sequelae of PID and ectopic pregnancy.
- (D) Utilize pregnancy and STD diagnostic screening tests as biological markers to validate self-reported behaviors and to evaluate the impact of the behavioral intervention.
- (E) Assess the performance of non-invasive, non-culture-base screening tests for the detection of as *C. trachomatis* and *N. gonorrhoeae* by ligase chain reaction (LCR) technique on first void urine compared to standard tests applied to (invasive) endocervical and urethral specimens by the presence or absence of symptoms.

4. BODY

Overview

The research methods, results, and discussion are described below in relation to the Statement of Work for the grant period August 7, 2001-August 6, 2002. Overall plans for the extension for Year 6 of the project included the following tasks:

T-1 Period: Complete the basic analysis for the baseline data related to STDs (chlamydia, gonorrhea, trichomonas, bacterial vaginosis, and pregnancy), self-reported questionnaires for T-1), and prepared and submitted and presented abstracts describing the baseline data to scientific meetings.

T-2 Period: Complete the basic analysis for the data for the second data collection period including data related to STDs (chlamydia, gonorrhea, trichomonas, bacterial vaginosis, and pregnancy), self-reported questionnaires for T-2), and prepared and submitted and presented abstracts describing the baseline data to scientific meetings.

T-3 Period: Complete a second follow-up (T-3) on all of the participating women Marines including the self-reported questionnaire and first void urine specimens for *C. trachomatis*, *N. gonorrhoeae*, and pregnancy screening. Complete data entry and cleaning of data from the questionnaire and for the biologic specimens. Begin the initial analyses for this data set including evaluation of the efficacy of the experimental (*FOCUS*) and control (*Fitness for Life*) intervention programs to prevent STDs and unplanned pregnancies.

STATEMENT OF WORK (SOW)

The following summarizes progress on the SOW activities:

- (A) Select a group of surface destroyer and submarine tender ships to focus initial data collection of which two ships will be targeted as study ships for the current study.

COMPLETED

1. The target population for implementation of the project is US Marine Corps Recruits from the Marine Corps Recruiting Depot (MCRD), Recruit Training Regimen (RTR) on Parris Island, SC. To date, we have approached 2,228 women Marine recruits to participate in the *FOCUS-Fitness for Life* intervention. Of these women 94% voluntarily consented to participate in the program (N=2,157). Of these women, 49% were assigned to the *FOCUS* program and 51% were assigned to the *Fitness for Life* program. The intervention component (T-1) of the program is finished with 1,916 women completing the intervention and graduating from recruit training (89% of those enrolled); (213) were discharged from Recruit Training.)
2. The Marine Combat Training (MCT) component of data collection (T-2) at Camp LeJeune, NC. At this initial follow-up, the participants were screened for pregnancy and STDs (chlamydia, gonorrhea, trichomonas) and completed a short interim behavioral questionnaire. A total of 1,748 women completed T-2, which represents 81% of those originally enrolled at T-1 (91% of those who completed T-1).

3. A second follow up (T-3) of the participants was completed December 2001 (begun July 1, 2000). We established follow-up sites on Okinawa, Japan (Camp Hansen, Camp Lester and others), in Jacksonville NC (Camp LeJeune, Camp Geiger, and others), and southern California (Camp Pendleton, 29 Palms, San Diego) to reach the women Marine participants who were assigned to duty stations in and around these regions. The women were screened for pregnancy, STDs (chlamydia, gonorrhea, trichomonas), and completed a self-reported behavioral questionnaire. In addition to these locations, MCRD at Parris Island, SC served as the coordinating site to reach women who were stationed in other regions of the country and abroad beyond our formal established research sites. These women completed a second-follow-up questionnaire and not the clinical specimen collections since it was not possible to transport these specimens from so many places adequately. 1,381 women were followed at T-3 representing 72% of those who completed the T-1 assessment.

- (B) Brief the Commanding Officers (COs) of the target populations.

COMPLETED

When the final data are analyzed, we plan to brief the Marine Command at Parris Island of the results and implications.

- (C) Conduct elicitation research (focus groups) in order to develop a self-report question to assess knowledge, attitudes, and beliefs, and behaviors of the target population and to develop a military-specific behavioral intervention to reduce risk or UIPs and STDs in the target population, including development, implementation, and evaluation of the intervention. (This includes all of our analyses evaluating the baseline descriptive data, the biologic STD test efficacy evaluations, and the evaluation of the efficacy of the actual cognitive, behavioral and skills building intervention FOCUS compared to FITNESS FOR LIFE). This latter emphasis on analyses has been the focus for the past 12 months.

ONGOING

1. All program materials, including videos, training exercises, training materials, and evaluation (assessment) instruments were developed.
2. All study participants were enrolled into the *FOCUS-Fitness for Life* intervention program as described above in section A-1 (T-1).
3. MCT follow-up phase (T-2) of the study was completed in January 2001. This phase includes 1,748 women as described in section A-2 above.
4. The second follow-up (T-3) of the study was completed in December 2001 as described above in sections A-3 above.

5. The initial analyses from baseline data from T-1 is described in the first published article and abstracts (Shafer, Boyer, Pang, et al. European Chlamydia Congress, Helsinki, Finland, 2000, Appendix 1a; Boyer, Shafer, Moncada et al. ISSTD: Sexually Transmitted Infections 241-246, 2001, Appendix 1b; Boyer and Shafer *Journal of Adolescent Health*, 30:129, 2002, Appendix 3c.)
- (D) Review STD logs and clinical records to establish the prevalence of reproductive health outcomes in the target population.
- COMPLETED**
1. All activities related to this task were completed prior to this fiscal year.
 2. We determined the baseline prevalence for *C. trachomatis*, *N. gonorrhoeae*, and *T. vaginalis* in the target population. We found an overall 13% rate of STD infections among entering Marine recruits including 11% infected with chlamydia, 2% with gonorrhea and 2% with trichomonas. (See Shafer, Boyer, Pang, et al. European Chlamydia Congress, Helsinki, Finland, 2000, Appendix 1a.)
 3. We determined that using Nugent's gram stain technique is a feasible method for use in a military setting and is able to determine accurately the presence of bacterial vaginosis which we found to be present in 1/3 of recruits with significantly more BV in ever sexually active compared to never sexually active young women (See Yen, Shafer, Moncada et al, SAM, 2003, Appendix 1e.)
- (E) Test the feasibility of non-invasive STD screening tests (urine) for chlamydia and gonorrhea in comparison to standard invasive tests.
1. All activities related to this task were completed prior to this fiscal year.
 2. We also determined the performance profiles for the 3 different collection methods to detect *C. trachomatis* and *N. gonorrhoeae* by nucleic acid amplification tests applied to endocervical, first catch urine, and self-administered vaginal swab specimens. (See Shafer, Boyer, Pang, et al. European Chlamydia Congress, Helsinki, Finland, 2000, Appendix 1a.) In addition, we evaluated the efficacy of applying the Nugent's gram stain technique to the diagnosis of bacterial vaginosis (BV) and compared results with results from a pH test card and the Papanicolaou smear. This paper was an oral presentation presented at the annual meeting of the Society of Adolescent Medicine by a fellow of Drs. Shafer and Boyer (Dr. Yen) in March 2002 (See abstract by Yen, Shafer, Moncada et al, JAH, 2002, Appendix 1c. and Yen, Shafer, Moncada et al, JAH, 2003, Appendix 1e.)
- (F) Test the acceptability of screening for pregnancy in the target population.
- COMPLETED**

5. KEY RESEARCH ACCOMPLISHMENTS TO DATE

- (A) Designed and successfully implemented an intense 8 hour training program within a complex recruit training schedule to decrease STDs and unplanned pregnancies.
- (B) Showed the feasibility of implementing an intense cognitive-behavioral intervention to decrease STDs and unplanned pregnancies in the military setting.
- (C) Showed the feasibility of implementing a universal STD and pregnancy screening program using multiple collections over time within the military setting.
- (D) Determined the feasibility of following individual participants over 3 different time periods during their first enlistment tour.
- (E) Described basic reproductive health behaviors including sexual activity, sexual partner information, contraceptive use, and other behavioral risk factors.
- (F) Determined the prevalence rates for common STDs among Marine women recruits: *C. trachomatis* (11%), *N. gonorrhoeae* (2%), and *T. vaginalis* (2%).
- (G) Evaluated the performance profiles of three different techniques for collecting STD specimens (endocervical, first part urine and self-administered vaginal swabs) and determined that vaginal or a combination of endocervical and vaginal detect the most infections and showed that the self-administered vaginal swabs had the highest performance for identifying chlamydia compared to the endocervix and urine specimens.
- (H) Determined that self-administered vaginal swabs are acceptable to this population of young women.
- (I) Determined that 92% of the Papanicolaou smears were entirely normal and 8% had evidence of HPV (human papillomavirus infection) with no cancer identified.
- (J) Age, partner's race at last sex, perception that sexual partners had other partners, birth control use and STD related symptoms at baseline screening were associated with a STD diagnosis at baseline analyzing the data using logistic regression techniques.
- (K) Young women Marines are placing themselves at great personal and health risk for acquisition of STDs and unplanned pregnancy and need interventions to prevent untoward health events, which may threaten their military readiness.

6. REPORTABLE OUTCOMES

- (A) Developed and produced a complete manual describing "how to" implement the FOCUS/FITNESS FOR LIFE interventions.
- (B) Produced a skills building teaching video entitled, "GOOD TO GO" as a part of this project, which is being used in the intervention training.
- (C) Developed a computerized and manual system for tracking recruits throughout their first enlistment.
- (D) Assisted the 4th Battalion, at the Marine Corps Recruiting Depot, Parris Island, SC to adopt and implement portions of the FOCUS intervention into their overall recruit training for women Marines.
- (E) Publications and presentations during past 12 months (See Appendices 1 and 3):
 - 1. Boyer CB, Shafer MA. Preventing STDs and unplanned pregnancies: A cognitive-behavioral intervention for young women entering the military. To be presented at the Annual meeting of the Society for Adolescent Medicine, Seattle, WA, March 2003. (Appendix 1d)
 - 2. Yen S, Shafer MA, Moncada J, Boyer, CB. Prevalence of bacterial vaginosis by Nugent's criteria in a non-clinic sample of young women entering the military: Relationships with sexual experience, vaginal symptoms and signs. To be presented at the Annual meeting of the Society for Adolescent Medicine, Seattle, WA, March 2003. (Appendix 1e)
 - 3. Yen S, Shafer MA, Moncada J, Campbell HC, Henry LC, Flinn K, Flinn S, Boyer CB. How common is bacterial vaginosis (BV) and how good are the tests: comparing Femexam^(R) PH, amine testcard and Papanicolaou smear to Nugent's criteria in a non-clinic population of young female military recruits, *Journal of Adolescent Health*, 30(2): 97-98, 2002.
 - 4. Boyer CB, Shafer MA: Development of a cognitive-behavioral group randomized control intervention trial to prevent STDs and unplanned pregnancies for young women entering the US military. Annual meeting of the Society for Adolescent Medicine, Boston MA, March 2002. (Appendix 3c)
 - 5. Boyer CB, Shafer MA, Betsinger K, Shaffer RA, Brodine SK, Kraft H, Schachter J: Preventing HIV, STDs, and unplanned pregnancies in young women entering the US military: A cognitive-behavioral approach. 2001 National HIV Prevention Conference, Atlanta, Georgia, August 12-15, 2001.

6. Boyer CB, Shafer MA, Moncada J, Schachter J, Shaffer RA, Brodine SK: Sociodemographic, behavioral, and clinical factors associated with STDs in a national sample of women entering the US military. *ISSTD: Sexually Transmitted Infections* 241-246, 2001. (Appendix 1b)
7. Boyer CB, Shafer MA, Pollack L, Kraft H: Sexually transmitted disease acquisition in a national, non-clinical, diverse sample of young women: associations of sociodemographic, behavioral, and clinical factors. Proceedings of The Society of Behavioral Medicine's 22nd Annual Meeting, Seattle, Washington, March 21-24, 2001.
8. Shafer MA, Boyer CB, Pang F, Moncada J, Dubovtsev A, Brodine S, Shaffer R, Schachter J. Comparison of 3 specimen collection techniques – endocervical and self-administered vaginal swab to screen for *C. trachomatis* (CT) and *N. gonorrhoeae* (GC) by NAATS in women Marine Recruits. IV European Chlamydia Congress, Chlamydia 2000, Helsinki, Finland, August 2000. (Appendix 1a)

7. CONCLUSIONS TO DATE:

- (A) Implementation of an intense cognitive-behavioral intervention to decrease acquisition of STDs and unplanned pregnancy is possible within a military setting.
- (B) Implementation of a universal STD and pregnancy screening program is possible within a military setting over time.
- (C) Asymptomatic and undetected STDs especially *C. trachomatis* are common among young women entering the U.S. Marines.
- (D) Young women Marines are placing themselves at risk for acquisition of STDs and unplanned pregnancy by engaging in risky sexual behaviors including having unprotected sexual intercourse, having sexual intercourse with multiple partners, among other risky behaviors.
- (E) It is critical to develop an annual universal STD screening program for STDs to be implemented immediately among young military women.
- (F) Early findings of high rates of STDs and risky behaviors linked to STD acquisition and unplanned pregnancy dictate that the implementation of an STD unplanned pregnancy prevention program for young women Marines is essential to support combat readiness.

PROPOSED PROJECT ACTIVITIES: AUGUST 2002-AUGUST 2003

Description of the Proposed Extension of Contract Activities To Be Completed:

(A) Continue cleaning questionnaire, tracking, and clinical data from all phases of the study.

(B) Data analyses from all study periods are ongoing.

(C) Drs. Boyer and Shafer and their colleagues are working on the following manuscripts:

1. Title: Sociodemographic, behavioral and clinical factors associated with STDs in a national sample of women entering the US military.

Authors: Cherrie B. Boyer, Mary-Ann Shafer, Julius Schachter, Richard Shaffer, Stephanie Brodine, Jesse Canchola, Lance Pollack.

Purpose: The purpose of this paper is to determine the relationship of sociodemographic risk markers, behavioral risk, and clinical factors to acquisition of STDs in women from through out the US entering recruit training for the military.

2. Title: Predicting sexual risk, STD history, and acquisition of STDs using the Information, Motivation, and Behavioral Skills (IMB) model.

Authors: Cherrie B. Boyer, Mary-Ann Shafer, Lance Pollack, Heidi Kraft

Purpose: To examine the extent to which information, psychosocial factors, including perceived vulnerability behavioral intentions, peer norms, behavioral skills are associated sexual risk behaviors, STD and pregnancy history, and STD acquisition.

3. Title: Comparison of 3 specimen collection techniques: Endocervical, first catch urine and self-administered vaginal swabs to screen for *C. trachomatis* (CT) and *N. gonorrhoeae* (GC) by NAATS in military women.

Authors: Mary-Ann Shafer, Cherrie B. Boyer, Franke Pang, Jeanne Moncada, Kim Flinn, Scott Flinn, Julius Schachter

Purpose: To determine the performance profile of 3 specimen collection methods to detect CT and GC by NAATS applied to endocervical, first catch urine, and self-administered vaginal swabs specimens in women Marine recruits.

4. Title: Are routine pelvic exams necessary annually in healthy sexually active young adults? STD screening and Papanicolaou smears in military recruits—an “ideal” national sample

Authors: Mary-Ann Shafer, Cherrie B. Boyer, Kelli Betsinger, Julius Schachter

Purpose: To determine the efficacy of routine pelvic examinations for STDs and cytopathology in healthy, sexually experienced young women. Specifically we will seek to understand what is the longitudinal clinical history of abnormal Pap smears identified at baseline, i.e., are they appropriately triaged and followed up according to the guidelines of the American Cancer Society including Pap smears and colposcopy at appropriate intervals?

5. Title: How common is bacterial vaginosis (BV) and how good are the testes? Comparing fexexam^R Ph-Amine TestCardTM and Papanicolaou smear to Nugent's criteria in a non-clinic population of young female military

Authors: Sophia Yen, Mary-Ann Shafer, Jeanne Moncada, Christopher Campbell, Charles Henry, Scott Flinn, Cherrie B. Boyer

(D) Present data at scientific meetings, 2003.

1. Boyer CB, Shafer MA. Preventing STDs and unplanned pregnancies: A cognitive-behavioral intervention for young women entering the military. Paper to be presented at the annual meeting of the Society for Adolescent Medicine, Seattle, WA, March 2003. (See Appendix 1d.)

2. Yen S, Shafer MA, Moncada J, Boyer, CB. Prevalence of bacterial vaginosis by Nugent's criteria in a non-clinic sample of young women entering the military: Relationships with sexual experience, vaginal symptoms and signs. Paper to be presented at the annual meeting of the Society for Adolescent Medicine, Seattle, WA, March 2003. (See Appendix 1e.)

(E) Write and submit a new proposal of research based on and extending the findings from the current work.

8. References

1. Yen S, Shafer MA, Moncada J, Campbell CJ, Flinn SD, and Boyer CB. Prevalence and Clinical Correlates of Bacterial Vaginosis Among Young Women Entering the Military. Submitted to *Obstetrics & Gynecology*, 2003.
2. Shafer MA, Moncada J, Boyer CB, Betsinger K, Flinn SD, Schachter J. Comparing the FVU, Self-collected Vaginal Swabs and Endocervical Specimens to Detect *C. trachomatis* And *N. gonorrhoeae* using Nucleic Acid Amplification Tests. Submitted to the *Journal of Clinical Microbiology*, 2003.
3. Yen S, Shafer MA, Moncada J, Campbell HC, Henry LC, Flinn K, Flinn S, Boyer CB. How common is bacterial vaginosis (BV) and how good are the tests: comparing Femexam^(R) PH, amine testcard and Papanicolaou smear to Nugent's criteria in a non-clinic population of young female military recruits, *Journal of Adolescent Health*, 30(2): 97-98, 2002.
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Publications to Date from the Project (See 6.D. Reportable Outcomes, 1-8)

1. Yen S, Shafer MA, Moncada J, Campbell HC, Henry LC, Flinn K, Flinn S, Boyer CB. How common is bacterial vaginosis (BV) and how good are the tests: comparing Femexam^(R) PH, amine testcard and Papanicolaou smear to Nugent's criteria in a non-clinic population of young female military recruits, *Journal of Adolescent Health*, 30(2): 97-98, 2002.
2. Boyer CB, Shafer MA: Development of a cognitive-behavioral group randomized control intervention trial to prevent STDs and unplanned pregnancies for young women entering the US military. Annual meeting of the Society for Adolescent Medicine, Boston MA, March 2002. (Appendix 3c)
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6. Shafer MA, Boyer CB, Pang F, Moncada J, Dubovtsev A, Brodine S, Shaffer R, Schachter J. Comparison of 3 specimen collection techniques – endocervical and self-administered vaginal swab to screen for *C. trachomatis* (CT) and *N. gonorrhoeae* (GC) by NAATS in women Marine Recruits. IV European Chlamydia Congress, Chlamydia 2000, Helsinki, Finland, August 2000. (Appendix 1a)

Appendices

1. Selected Abstracts For Scientific Meetings
2. Brief, August 2002, Presented to Major General Lester Martinez-Lopez, M.D., MPH., at Fort Detrick, Fredrick MD
3. Presentations/Scientific Meetings

Appendix 1.

Selected Abstracts For Scientific Meetings

- a. Shafer MA, Boyer CB, Pang F, Moncada J, Dubovtsev A, Brodine S, Shaffer R, Schachter J. Comparison of 3 specimen collection techniques – endocervical and self-administered vaginal swab to screen for *C. trachomatis* (CT) and *N. gonorrhoeae* (GC) by NAATS in women Marine Recruits. IV European Chlamydia Congress, Chlamydia 2000, Helsinki, Finland, August 2000.
- b. Boyer CB, Shafer MA, Moncada J, Schachter J, Shaffer RA, Brodine SK: Sociodemographic, behavioral, and clinical factors associated with STDs in a national sample of women entering the US military. Presented at the 2001 ISSTD Congress, Berlin, Germany, June 24-27, 2001; ISSTD: Sexually Transmitted Infections 241-246, 2001.
- c. Yen S, Shafer MA, Moncada J, Campbell HC, Henry LC, Flinn K, Flinn S, Boyer CB. How common is bacterial vaginosis (BV) and how good are the tests: comparing Femexam^(R) PH, amine testcard and Papanicolaou smear to Nugent's criteria in a non-clinic population of young female military recruits. Journal of Adolescent Health, 30(2):97-98, 2002.
- d. Boyer CB, Shafer MA. Preventing STDs and unplanned pregnancies: A cognitive-behavioral intervention for young women entering the military. To be presented at the Annual meeting of the Society for Adolescent Medicine, Seattle, WA, March 2003
- e. Yen S, Shafer MA, Moncada J, Boyer, CB. Prevalence of bacterial vaginosis by Nugent's criteria in a non-clinic sample of young women entering the military: Relationships with sexual experience, vaginal symptoms and signs. To be presented at the Annual meeting of the Society for Adolescent Medicine, Seattle, WA, March 2003

Official Abstract Form

COMPARISON OF 3 SPECIMEN COLLECTION TECHNIQUES-ENDOCERVICAL, FIRST CATCH URINE AND SELF-ADMINISTERED VAGINAL SWAB TO SCREEN FOR *C.TRACHOMATIS* (CT) AND *N.GONORRHOEAE* (GC) BY NAATS IN WOMEN MARINE RECRUITS.

MA Shafer¹, C Boyer¹, F Pang,² J Moncada², A Dubovtsev¹, S Brodine³, R Shaffer³, J Schachter²
University of California, San Francisco, Departments of Pediatrics¹ and Laboratory Medicine²; Naval Health Research Center, San Diego, CA³.

Objective: To determine the performance profile of 3 specimen collection methods to detect CT and GC by NAATs applied to endocervical (Cx), first catch urine (FCU) and self-administered vaginal swab (Vag) specimens in women Marine recruits.

Methods: At entry into the military, all women Marine recruits are screened for cervical CT and GC using LCx^R (Abbott) and have Pap smears taken during routine pelvic exams which are processed by a military contract laboratory. To date, 1110 women have voluntarily consented to participate in a behavioral intervention to prevent STD acquisition and unintended pregnancy; 6% refused participation. All participants completed a self-report survey and provided a FCU and 3 self-administered vaginal swabs for screening for CT and GC using LCx^R (Abbott). An additional vaginal swab was obtained for *T.vaginalis* (TV) culture (*Trich In- Pouch*^R).

Results: Analyses were based on 796 sexually experienced women who had all 3 specimens tested. Ss had a mean age of 18.8 years, were ethnically diverse (55% W, 21% H, 17% Af Am, 7% As/Other), and largely never-married (92%). 13% reported a history of pregnancy and 8% reported a history of an STD(s). In the past 3 months, 15% reported sexual activity, and 25% had ≥ 2 partners. Currently, 40% used hormonal birth control, 76% used condoms, and 25% complained of genital symptoms on clinical history.

127(16%) of infections were identified:
90(11%) CT, 21(3%) GC, 16 (2%) TV.

Table: Sensitivities for CT and GC by Collection Method (N=796)

<i>C.trachomatis</i>		
<u>Cx</u> 68%	<u>FCU</u> 72%	<u>Vag</u> 88%
<u>Cx+FCU</u> 86%	<u>Vag+FCU</u> 94%	<u>Cx+Vag</u> 97%
<i>N.gonorrhoeae</i>		
<u>Cx</u> 43%	<u>FCU</u> 32%	<u>Vag</u> 81%
<u>Cx+FCU</u> 52%	<u>Vag+FCU</u> 86%	<u>Cx+Vag</u> 100%

Conclusion: STDs are common among young women Marine recruits. Vaginal swabs proved to be the best single method for identifying CT and GC. Urine performed poorly in identifying CT and GC. Combining 2 collection methods improved the sensitivities with the Cx+Vag combination yielding the best results for identifying CT and GC. Consequently, when screening during a pelvic exam, it appears that the simultaneous sampling of the cervix and vagina, e.g., one swab at endocervix followed by a "spiral" sampling technique of the vagina on exiting, would likely identify the most CT and GC infections without increasing clinician time or costs.

Preferred presentation format (please check):

Oral ☒ Poster ☐ Topic preference ☐ Diagnostics ☐

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I hereby authorise the publication of this abstract in the congress proceedings and the title with names of authors in the website.

SOCIODEMOGRAPHIC, BEHAVIORAL, AND CLINICAL FACTORS ASSOCIATED WITH STDs IN A NATIONAL SAMPLE OF WOMEN ENTERING THE US MILITARY
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Objective: To determine the relationship of sociodemographic risk markers, behavioral risk, and clinical factors to acquisition of STDs in women from throughout the United States entering recruit training for the military. **Methods:** Participants were screened for chlamydia and gonorrhea using LCxTM applied to urine, vaginal swabs, and cervical specimens, and trichomonas using InPouch TVTM. Participants also completed a self-reported questionnaire to assess sociodemographic risk markers (age, race/ethnicity, marital status, education, sexual partner characteristics), behavioral risk (e.g., number of sexual partners, casual sex, use of birth control), and clinical factors (history of pregnancy and STDs, STD-related symptoms). **Results:** The participants were 2,157 women (mean age = 19.2 years) of diverse racial/ethnic background (Caucasian 58%, Latino 20%, African American 16%, Other 6%) who were primarily single (90%), sexually experienced (85%) and at risk for STDs, 16% had a history of pregnancy and 12% had STDs. In the three months prior to the study, 29% had ≥ 2 partners, 57% used alcohol/substances before/during sex, 56% did not use birth control and 73% did not use condoms consistently; 48% perceived their partners had other partners. At screening, 24% had vaginal symptoms, and 13% were positive for an STD (11% chlamydia, 2% gonorrhea, 2% trichomonas). Sociodemographic risk markers, behavioral risk in the three months prior to the study, and STD-related symptoms were entered into a backward stepwise logistic regression. Age [≤ 18 vs. 19-20 (OR=1.53, CI = 1.05-2.24); ≥ 21 vs. 19-20 (OR = 1.81, CI = 1.11-2.95)], partner's race at last sex [African American vs. White (OR= 4.44, CI = 3.11-6.34)], perception that their sexual partners had other partners (OR = 1.43, CI = 1.04-1.97), frequency of birth control [Usually/Always vs. Almost Never/Never (OR = 1.92, CI = 1.17-3.15)], and presence of STD-related symptoms at screening (OR = 1.51, CI = 1.07-2.12) were significantly associated ($p < .05$) with an STD diagnosis. **Conclusions:** The high prevalence of STDs in this national, non-clinical sample of young women suggest the need for ongoing prevention interventions, including STD screening and behavioral risk reduction programs that target non-college students.

HOW COMMON IS BACTERIAL VAGINOSIS (BV) AND HOW GOOD ARE THE TESTS: COMPARING FEMEXAM® PH-AMINE TESTCARD™ AND PAPANICOLAOU SMEAR TO NUGENT'S CRITERIA IN A NON-CLINIC POPULATION OF YOUNG FEMALE MILITARY RECRUITS. Sophia Yen, M.D., Mary-Ann Shafer, M.D., Jeanne Moncada, MS, HM1 Christopher Campbell, LTCDR Charles Henry, Kimberly Flinn, RN, Scott Flinn, M.D., Cherrie B. Boyer, Ph.D. Dept. of Pediatrics, Dept of Laboratory Medicine, University of California, San Francisco. CA; Beaufort Naval Hospital, Beaufort, S.C.

Purpose: To determine the prevalence of bacterial vaginosis (BV) by Nugent's Gram stain criteria in an ethnically diverse, non-clinic young female sample; and to determine the sensitivity and specificity of an amines and pH colorimetric test and Papanicolaou smear for the diagnosis of BV compared to Nugent's Gram stain criteria.

Methods: A cross-sectional study was conducted with 2157 young women entering recruit training for the military representing 95% of those approached. Of these, 1944 had complete clinical data available for analysis (specimens were eliminated if there was blood on a swab). Participants actively consented to participate in a longitudinal intervention to prevent STD acquisition and unintended pregnancy. Data were derived from STD screening performed at baseline. Prior to their routine pelvic exam, the women self-administered two vaginal swabs that were placed in a plastic tube, transported to the research laboratory, and processed within 10 minutes of collection. One swab was placed on the *FemExam® pH and Amine TestCard™*. The tests were read within 2 minutes of placement for pH and the presence of amines; positive tests were determined by a trained research assistant by colorimetric change on the cards. The second swab was used for Gram stain specimens that were read by a trained laboratory technician who was blinded to clinical findings. A positive test for BV was a Nugent score ≥ 7 . Papanicolaou smears were sent routinely to the clinical laboratory to be read.

Results: 1944 Ss were included in the analysis with a mean age of 19.0 years and race/ethnicity of 56%Cauc, 20% Hisp/Lat, 16% Af Am, 9% As/Oth; 86% were sexually active. *Clinical:* At examination, 19% self-reported vaginal discharge and 7% abnormal vaginal odor while clinicians reported 5% abnormal discharge. *Laboratory:* 27% were BV(+) by Nugent's criteria and 29% had clue cells/vaginitis identified on routine Papanicolaou smear. *FemExam®* results showed Ss were 33% pH (+) and 6% amine (+). In addition, BV by Nugent's criteria was significantly related to: a history of sexual activity, presence of clue cells on Papanicolaou smear, and amine (+) and pH (+) by *FemExam®* (all at $p < .0001$). The sensitivity/specificity using Nugent's criteria as the standard were 72%/67% for pH and 11%/97% for amines portions of the *FemExam®*, and 72%/79% for clue cells/vaginitis on Papanicolaou smear cytology.

Conclusion: BV occurs commonly among young women entering military recruit training. Although highly related to diagnosis by Nugent's criteria, pH (*FemExam®*) and Papanicolaou smear cytology performed moderately well while the amines (*FemExam®*) performed poorly as individual BV diagnostic tools. As the importance of the role of BV in reproductive morbidity in young women becomes more defined, it will become important to continue developing and evaluating simple "bedside" tests.

PREVENTING STDs AND UNPLANNED PREGNANCIES: A COGNITIVE-BEHAVIORAL INTERVENTION FOR YOUNG WOMEN ENTERING THE U.S. MILITARY

Cherrie B. Boyer, Ph.D. and Mary-Ann Shafer, M.D., University of California, San Francisco, Department of Pediatrics, Division of Adolescent Medicine, San Francisco, California

Purpose: The purpose is to evaluate the feasibility and effectiveness of a cognitive-behavioral intervention to prevent sexually transmitted diseases (STDs) and unplanned pregnancies (UIPs) in young women from throughout the United States entering military recruit training between June 1999 and June 2000.

Methods: Study Design: A randomized control trial with assessments at baseline and 9-12 months post intervention. **Setting:** U.S. military recruit training center. **Participants:** A large, national, non-clinic sample of adolescent and young adult women. 2157 voluntarily agreed to participate (94% consent rate); 1062 (49%) and 1095 (51%) were assigned to intervention and control conditions, respectively.

Interventions: Guided by the Information, Motivation, and Behavioral Skills (IMB) Model, the experimental intervention consisted of 4, 2-hour interactive and didactic group sessions on (small group format): information, reproductive anatomy, contraceptive methods, alcohol/other substances, peer norms, self-efficacy, behavioral intentions, and skills-building strategies to enhance communication and problem-solving skills. The control group condition was conducted in a similar format and focused on improving the participants' physical performance through promoting healthier food choices and preventing physical training injuries. **Risk Groups:** For the analysis, women were grouped into 4 risk groups (no, low, moderate, high) using a number of STD risk factors (number of sexual partners, consistency of condom use, and history of pregnancy and/or STDs). **Outcome Measures:** STDs, UIPs and sexual behaviors.

Results: The participants were primarily young, (mean age=19.2 years), single (93%), diverse (43% non-Caucasian), sexually experienced (85%) and at risk for STDs: 59% had sex ≤ 16 years, 82% had ≥ 2 sexual partners, 57% used substances before/during sex, 56% did not use birth control, 73% used condoms inconsistently, 16% had a history of pregnancy and 12% had STD(s); 48% perceived partners had other partners. At STD screening, 24% had vaginal symptoms and 14% were positive for one or more STDs (11% *C. trachomatis*, 2% *N. gonorrhoeae*, 2% *T. vaginalis*). 1,382 women (72% of those who completed the intervention) were followed 9-12 months post-intervention. Significant group differences were found among a sub-group of the women at follow-up. Specifically, women who were categorized, at baseline, to be at 'moderate risk' (reported multiple sexual partners, inconsistent condom use, and no history of either pregnancy or STDs) were 2.3 times more likely than the intervention group to be diagnosed with an STD (OR=2.3, CI-2.3-3.9).

Conclusions: The high prevalence of sexual risk behaviors and STDs in this national, non-clinical, sample of young women suggest the need for ongoing STD prevention programs for young women post high school. Moreover, the findings of this randomized controlled trial indicate that multi-session, cognitive-behavioral interventions are feasible and effective strategies for preventing STDs in at risk women. Finally, this study represents the first and largest successful intervention of its kind.

PREVALENCE OF BACTERIAL VAGINOSIS (BV) BY NUGENT'S CRITERIA IN A NON-CLINIC NATIONAL SAMPLE OF YOUNG WOMEN ENTERING THE MILITARY: RELATIONSHIPS WITH SEXUAL EXPERIENCE, VAGINAL SYMPTOMS AND SIGNS

Sophia Yen, M.D., Mary-Ann Shafer, M.D., Jeanne Moncada, M.S., Cherrie B. Boyer, Ph.D., Dept. of Pediatrics, Dept of Laboratory Medicine, University of California, San Francisco, CA.

Purpose: To determine and compare the prevalence of bacterial vaginosis (BV) by Nugent's Gram stain criteria in a racially and ethnically diverse, non-clinic young adult female sample between sexually-experienced and sexually-inexperienced young women, and to determine the clinical correlates of a BV diagnosis.

Methods: A cross-sectional study of a voluntary sample of 2157 young women from throughout the United States entering military recruit training was conducted as a part of a larger behavioral-cognitive study designed to prevent STDs and unintended pregnancy. Self-administered vaginal swabs were applied to a glass slide for Gram stain. A positive test for BV was defined by a Nugent score ≥ 7 .

Results: Participants with complete data included in the analysis were 1938 women with a mean age of 19.1 years, a diverse racial/ethnic profile (56% Caucasian, 20% Hispanic, 16% African American, 3% Asian/Pacific Islander, 2% Native American, 2% Other/Mixed); 86% were sexually experienced. *Clinical:* At examination, 20% self-reported vaginal discharge and 7% self-reported vaginal odor, while clinicians noted vaginal discharge in 5%.

Laboratory: 27% were BV (+) by Nugent's criteria (28% in those sexually-experienced, 18% in not sexually-experienced. In addition, BV by Gram stain was positively related to: a history of sexual activity, self-report of vaginal discharge, self-report of vaginal odor and current diagnosis of *C. trachomatis* (all $p < .003$). BV diagnosis was inversely related to hormonal contraceptive use ($p = .013$). There was no significant difference in the proportion of those women with and without BV with respect to: self-report of vaginal itching, clinician detection of vaginal discharge, prior history of STD, >1 partner in the past three months and current diagnosis of *N. gonorrhoeae* or *T. vaginalis*.

Conclusion: BV occurs commonly among this sample of young women entering military recruit training in both the sexually-experienced and inexperienced. Young women's self-report of vaginal discharge and odor were highly correlated with a diagnosis of BV. Thus, clinicians should evaluate both sexually-experienced and inexperienced young women complaining of vaginal discharge and odor for BV. Further studies are needed to elucidate the relationship of BV with *C. trachomatis* and hormonal contraceptives.

Appendix 2.

Brief, 2002

**Presented to Major General Lester Martinez-
Lopez, M.D., MPH., at Fort Detrick, Fredrick
MD August 2002**

FOCUS

Cherrie B. Boyer, Ph.D.
Mary-Ann Shafer, M.D.
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CDR Richard A. Shaffer, Ph.D.
LT Heidi S. Kraft, Ph.D.
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Naval Health Research Center, San Diego, CA



UCSF

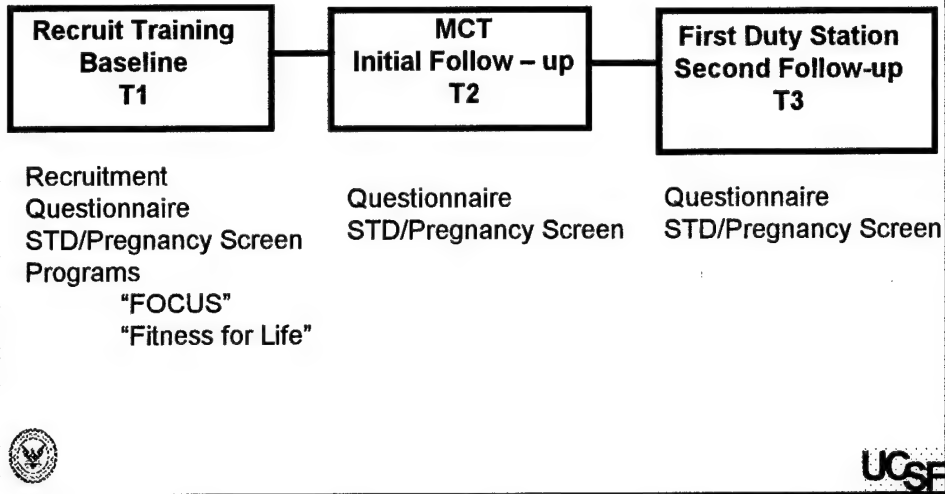
PROGRAM OBJECTIVE

To evaluate the feasibility and effectiveness of a cognitive-behavioral intervention to prevent and reduce the risk of HIV/STDs and unplanned pregnancies in young women entering recruit training for the Marine Corps

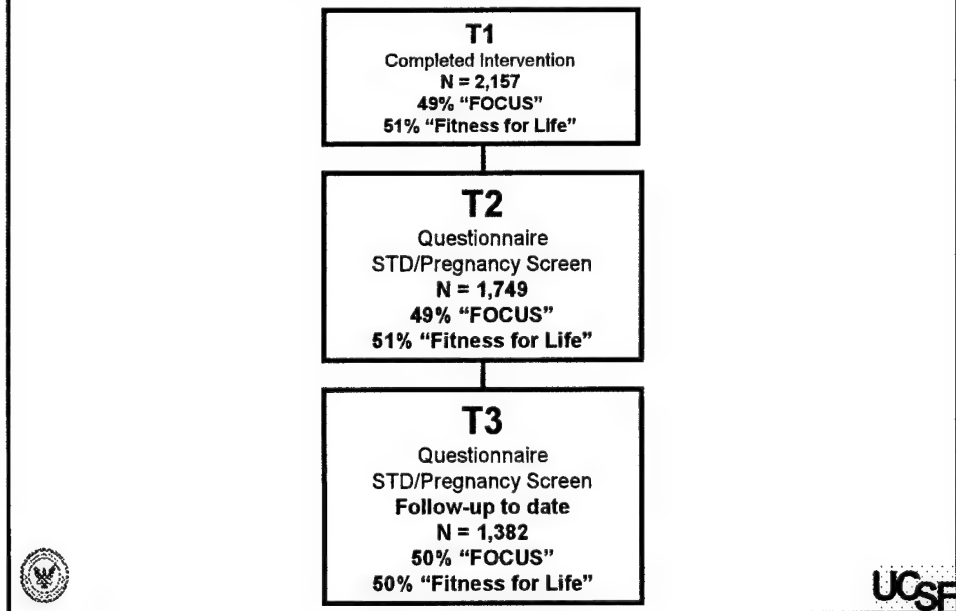


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STUDY DESIGN



INTERVENTION & FOLLOW-UP



SOCIODEMOGRAPHIC MARKERS

	<u>T1</u> (N=2157)	<u>T3</u> (n=1382)
Age		
17-18	54%	56%
19-20	31%	30%
≥ 21	15%	14%
Race/Ethnicity		
Caucasian	56%	54%
Latina	20%	23%
African American	16%	15%
Other	8%	8%



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SOCIODEMOGRAPHIC MARKERS

	<u>T1</u> (N=2157)	<u>T3</u> (N=1382)
Marital Status		
Single	93%	95%
Level of Education		
High School Diploma/GED	75%	76%
Years of sexual experience		
≤ 1	26%	27%
≥ 2	74%	73%



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BEHAVIORAL RISK FACTORS

	<u>T1</u> (N=2157)	<u>T3</u> (n=1383)
Sexual Partners		
1	18%	19%
≥ 2	82%	81%
Casual Partners		
≥ 1	65%	65%
Frequency of Birth Control		
Never/Sometimes	33%	33%
Usually/Always	67%	67%
Condom Use		
< 100%	78%	77%



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BEHAVIORAL RISK FACTORS

	<u>T1</u> (N=2157)	<u>T3</u> (n=1383)
Heavy Drinking		
Yes	14%	
Sex Under the Influence of Alcohol/Substances		
Sometimes	47%	46%
Usually/Always	11%	10%



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STD PREVALENCES

<u>STD</u>	<u>T1</u> (N=2157)	<u>T3</u> (n=1383)
Chlamydia*	11%	11%
Gonorrhea*	2%	2%
Trichomonas**	2%	1%
Any Positive	14%	13%

* by LCx^R

** by Trich-In-Pouch^R (self-swab)



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DEFINITIONS OF GROUPS

No Risk (15.6%)	Not sexually experienced
Low Risk (20.4%)	Sexually experienced and no history of pregnancy/STDs ~AND~ Not sexually active in 3 months prior to RT OR Had sex in the past 3 months with 1 partner and 100% condom use
Moderate Risk (31.7%)	Sexually experienced and no history of pregnancy/STDs ~AND~ ≥2 sex partners in 3 months prior to RT OR < 100% condom use
High Risk (32.3%)	Had history of pregnancy/STDs



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EFFECTS OF INTERVENTION ON STD ACQUISITION

Risk Group at T1	<u>% Positive</u>		Odds Ratio*
	Fitness	Focus	
No Risk	6%	8%	0.7
Low Risk	9%	10%	0.6
Moderate Risk	18%	10%	2.0*
High Risk	18%	21%	0.9



*Statistically significant at < 0.05 level

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Appendix 3.

Presentations/Scientific Meetings

- a. Shafer MA, Boyer CB, Pang F, Moncada J, Dubovtsev A, Brodine S, Shaffer R, Schachter J. Comparison of 3 specimen collection techniques – endocervical and self-administered vaginal swab to screen for *C. trachomatis* (CT) and *N. gonorrhoeae* (GC) by NAATS in women Marine Recruits. IV European Chlamydia Congress, Chlamydia 2000, Helsinki, Finland, August 2000.
- b. Yen S, Shafer MA, Moncada J, Campbell C, Henry C, Flinn K, Flinn S, Boyer CB: How common is bacterial vaginosis (BV) and how good are the tests: comparing FemExam® pH-amine Test-Card™ and Papanicolaou smear to Nugent's criteria in a non-clinic population of young military recruits. Annual meeting of the Society for Adolescent Medicine, Boston MA, March 2002.
- c. Boyer CB, Shafer MA: Development of a cognitive-behavioral group randomized control intervention trial to prevent STDs and unplanned pregnancies for young women entering the US military. Annual meeting of the Society for Adolescent Medicine, Boston MA, March 2002.

Appendix 3a.

Shafer MA, Boyer CB, Pang F, Moncada J, Dubovtsev A, Brodine S, Shaffer R, Schachter J. Comparison of 3 specimen collection techniques – endocervical and self-administered vaginal swab to screen for *C. trachomatis* (CT) and *N. gonorrhoeae* (GC) by NAATS in women Marine Recruits. IV European Chlamydia Congress, Chlamydia 2000, Helsinki, Finland, August 2000.

**COMPARISON OF 3 SPECIMEN
COLLECTION TECHNIQUES-
ENDOCERVICAL, FIRST CATCH URINE
AND SELF-ADMINISTERED VAGINAL
SWAB TO SCREEN FOR *C.TRACHOMATIS*
(CT) AND *N.GONORRHOEAE* (GC) BY
NAATS IN WOMEN MARINE RECRUITS.**

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A Dubovtsev¹, S Brodine³, R Shaffer³, J Schachter²
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Departments of Pediatrics¹ and Laboratory
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San Diego, CA³.

INTRODUCTION

Unprotected sexual intercourse results in major medical and social morbidities of STDs and unintended pregnancies (UIPs) that can uniquely threaten the combat readiness of military women. Reported chlamydial infection rates in this population range from 5-9% or more. Little data is available on the rates and relationships among STDs and health behaviors in this group.

This study represents the baseline clinical data of women Marine Corps recruits participating in an 8-hour, cognitive-behavioral, skills-building intervention (*FOCUS-FITNESS FOR LIFE*) to prevent STDs and UIPs.

Objectives

1. To determine the performance of 3 specimen collection methods to detect *C. trachomatis* and *N. gonorrhoeae* by nucleic acid amplification test applied to endocervical, first catch urine, and self-administered vaginal swab specimens.
2. To describe the prevalence of *C. trachomatis*, *N. gonorrhoeae* and *T.vaginalis* and to define the relationship between STDs detected at baseline, behavioral, and sociodemographic factors in this national sample of young women.

METHODS

Subjects: Young women entering 13 weeks of recruit training at the U.S. Marine Corps Recruiting Depot in Parris Island, SC were enrolled in the *FOCUS-FITNESS FOR LIFE* intervention. This study represents the first 1661 women who voluntarily consented to participate (6% declined).

Clinical Procedures: These recruits undergo a routine pelvic exam with STD and Pap smear screening within 2 weeks of arrival. The study questionnaire and specimen collection (cervical, FCU and 3 self-administered vaginal swab specimens) were incorporated into this exam.

1. ***Survey:*** A self-reported survey querying about behaviors, clinical history regarding STDs, pregnancy, and other risk factors were administered upon written, informed consent.

2. ***Specimens:*** Cervical, vaginal and FCU samples for *C.trachomatis* (CT) & *N.gonorrhoeae* (GC) were processed using LCxTM (Abbott). A vaginal swab was used for *T.vaginalis* (TV) using In-Pouch TVTM (Biomed). Cervical specimens were processed by military licensed labs; FCU and vaginal samples for CT/GC were processed in the lab of an author (JS); and TV was incubated @37° C and read at 2 and 5 days.

RESULTS

CONCLUSIONS

1. STDs (13%) are prevalent among young women entering the Marine Corps.
2. Only 40% used condoms at last sex.
3. Vaginal and endocervical swabs combined yielded the best sensitivity rates for CT & GC.
4. Vaginal swabs are the best single technique of the 3 possible techniques for CT & GC.
5. The performance of LcxTM to detect GC was poor with self-administered vaginal samples performing the best of 3 sites (72% sensitivity).

IMPLICATIONS

1. Young women entering Marine Corps recruit training represent a diverse ethnic/racial and geographical national sample for study of reproductive health issues.
2. Epidemic STD rates among these young women dictate the need for screening.
3. Prevention of risky sexual behaviors is urgently needed in this group.
4. A combination of endocervical and a spiral sampling of the vaginal wall may offer the best single technique for obtaining CT and GC samples during a pelvic exam.
5. Self-administered vaginal samples are the best single technique for detecting CT and GC in this young population of women.

**Table 1 Sociodemographics of Sexually
Active Women Marine Recruits (N=1414)**

Age (median = 18 years; range 17-33 yrs)

17 years	8%
18 years	46%
19 years	21%
20-33 years	25%

Race/Ethnicity

White	57%
Hispanic	19%
African American	15%
Other	9%

Marital Status

Never married	90%
Married	8%
Separated/divorced	2%

Table 2 Sexual Activity

Sexual Activity

Ever

N=1408/1646 (86%)

Sexual debut (median 16 yrs, range 6-25 yrs)

< 12 years 1%

12-15 years 35%

16-17 years 45%

>18-19 years 19%

Years sex active (median 3 yrs, range 1-16 yrs)

< 1 year 26%

2 years 22%

3 years 18%

4 years 13%

> 5 years 21%

Table 3 Pregnancy, STD, Partner Hx

Pregnancy ever	16%
-----------------------	------------

STD ever ("Told by MD")	10%
--------------------------------	------------

Partners in lifetime

1 partner ever	18%
-----------------------	------------

2-4 partners	39%
---------------------	------------

≥ 5 partners	43%
-------------------------------------	------------

Last 3 months

Did not have sex	13%
-------------------------	------------

1 partner	61%
------------------	------------

> 1 partner	26%
-----------------------	------------

≥ 1 Casual partner	25%
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**Table 4 Contraceptive Use at Last
Sexual Intercourse (%)**

No method only	19
Withdrawal only	12
OCPs (pills) only	13
Depo-Provera/Norplant only	5
Condoms only	40
Other only (spermicide only)	3
OCPs & condoms	6
Depo-Provera/Norplant & condoms	2

*** 15% (211/1414) did not have sex in past 3 mos**

Table 5 Prevalences of STDs

<u>Any STD</u>	13.0%
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<u>C. trachomatis</u> (any “+” by Lcx^R)	
---	--

Endocervix, urine, vagina*	11.6%
-----------------------------------	--------------

<u>N. gonorrhoeae</u> (any “+” by Lcx^R)	
---	--

Endocervix, urine, vagina	2.2%
----------------------------------	-------------

<u>T. vaginalis</u> (“+” by <i>Trich In Pouch</i>^R)	
---	--

Vaginal swab	1.6%
---------------------	-------------

*** Self administered vaginal swabs**

Table 6 Prevalences of STDs by Type of Specimen: Chlamydia*

C. trachomatis

Any positive	11.6%
Endocervix	7.5%
Urine	8.5%
Vagina*	10.0%

Sensitivity for C.trachomatis by specimen**

Endocervix	65%
Urine	73%
Vaginal*	83%
Endocervix <u>and</u> urine	86%
Endocervix <u>and</u> vagina*	91%
Vagina* <u>and</u> urine	95%

* Self-administered vaginal swab

** Positive result by any method

**Table 7 Prevalences of STDs by
Type of Specimen: *N.gonorrhoeae***

N.gonorrhoeae

Any positive	2.2%
Endocervix	1.1%
Urine	0.5%
Vagina*	1.7%

Sensitivity for *N.gonorrhoeae* by specimen

Endocervix	45%
Urine	24%
Vagina*	72%
Endocervix <u>and</u> urine	52%
Endocervix <u>and</u> vagina	100%
Vagina* and urine	76%

***Self-administered vaginal swab**

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Medicine²; Naval Health Research Center, San Diego, CA³.

Objective: To determine the performance profile of 3 specimen collection methods to detect CT and GC by NAATs applied to endocervical (Cx), first catch urine (FCU) and self-administered vaginal swab (Vag) specimens in women Marine recruits.

Methods: At entry into the military, all women Marine recruits are screened for cervical CT and GC using LCx^R (Abbott) and have Pap smears taken during routine pelvic exams which are processed by a military contract laboratory. To date, 1110 women have voluntarily consented to participate in a behavioral intervention to prevent STD acquisition and unintended pregnancy; 6% refused participation. All participants completed a self-report survey and provided a FCU and 3 self-administered vaginal swabs for screening for CT and GC using LCx^R (Abbott). An additional vaginal swab was obtained for *T.vaginalis* (TV) culture (*Trich In- Pouch*^R).

Results: Analyses were based on 796 sexually experienced women who had all 3 specimens tested. Ss had a mean age of 18.8 years, were ethnically diverse (55% W, 21% H, 17% Af Am, 7% As/Other), and largely never-married (92%). 13% reported a history of pregnancy and 8% reported a history of an STD(s). In the past 3 months, 15% reported sexual activity, and 25% had \geq 2 partners. Currently, 40% used hormonal birth control, 76% used condoms, and 25% complained of genital symptoms on clinical history.

127(16%) of infections were identified:
90(11%) CT, 21(3%) GC, 16 (2%) TV.

**Table: Sensitivities for CT and GC by
Collection Method (N=796)**

<i>C.trachomatis</i>		
<u>Cx</u> 68%	<u>FCU</u> 72%	<u>Vag</u> 88%
<u>Cx+FCU</u> 86%	<u>Vag+FCU</u> 94%	<u>Cx+Vag</u> 97%
<i>N.gonorrhoeae</i>		
<u>Cx</u> 43%	<u>FCU</u> 32%	<u>Vag</u> 81%
<u>Cx+FCU</u> 52%	<u>Vag+FCU</u> 86%	<u>Cx+Vag</u> 100%

Conclusion: STDs are common among young women Marine recruits. Vaginal swabs proved to be the best single method for identifying CT and GC. Urine performed poorly in identifying CT and GC. Combining 2 collection methods improved the sensitivities with the Cx+Vag combination yielding the best results for identifying CT and GC. Consequently, when screening during a pelvic exam, it appears that the simultaneous sampling of the cervix and vagina, e.g., one swab at endocervix followed by a "spiral" sampling technique of the vagina on exiting, would likely identify the most CT and GC infections without increasing clinician time or costs.

Appendix 3b.

Yen S, Shafer MA, Moncada J, Campbell HC, Henry LC, Flinn K, Flinn S, Boyer CB. How common is bacterial vaginosis (BV) and how good are the tests: comparing Femexam^(R) PH, amine testcard and Papanicolaou smear to Nugent's criteria in a non-clinic population of young female military recruits. Journal of Adolescent Health, 30(2):97-98, 2002.

**How Common is BV (Bacterial Vaginosis) and
How good are the Tests:
Comparing FemExam® pH-Amines Testcard
and Papanicolaou Smear to Nugent's Criteria
in a Non-Clinic Population of
Young Female Military Recruits**

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Project supported by:

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- LEAH Training grant #MC0003, Maternal & Child Health Bureau, HRSA, DHHS, who in part supported Drs. Boyer, Shafer, Yen

Bacterial Vaginosis (BV)

- Most common cause of vaginal d/c
- Prevalence: 7% - 46%
- Reproductive morbidity:
 - PID
 - Pre-term birth
 - PROM

BV Definitions

- Microbiology: *Lactobacillus* --> mixed flora
- Amsel's Criteria: (3 of 4 present)
 - Vaginal pH >4.5
 - Adherent white discharge
 - Clue cells by wet mount
 - Amine odor after KOH
- Nugent's Criteria: Gram stain criteria

Nugent's Criteria

- Gram stain of vaginal secretions
- Scored from 0 - 4 +:
 - Large gram (+) rods (*Lactobacillus*)
 - Small gram (-) to variable rods (*Gardnerella* and *Bacteroides* sp.)
 - Curved gram (-) rods (*Mobiluncus* sp.)
- Positive when score ≥ 7

Nugent et al. J Clin Microbiol. Feb 1991. 297-301.

Purpose

- Determine BV prevalence* in a diverse non-clinic sample of young women
- Evaluate the performance of a rapid “bedside” test card, the *FemExam*®
- Test the performance of Pap smears

* by Nugent's

Methods

Recruitment of sample:

- Voluntary sample of 2157 military recruits participating in an STD/pregnancy prevention program between July 1999 and July 2000
- Women from throughout the U.S.

Clinical Specimens

- Self-collected vaginal swabs
 - #1: FemExam[®]
 - #2: Nugent's
- FVU for GC, CT
- Pap smears

Amsel Criteria

- 1) Vaginal pH >4.5
- 2) Amine odor after KOH
- 3) Adherent white discharge
- 4) "Clue cells"

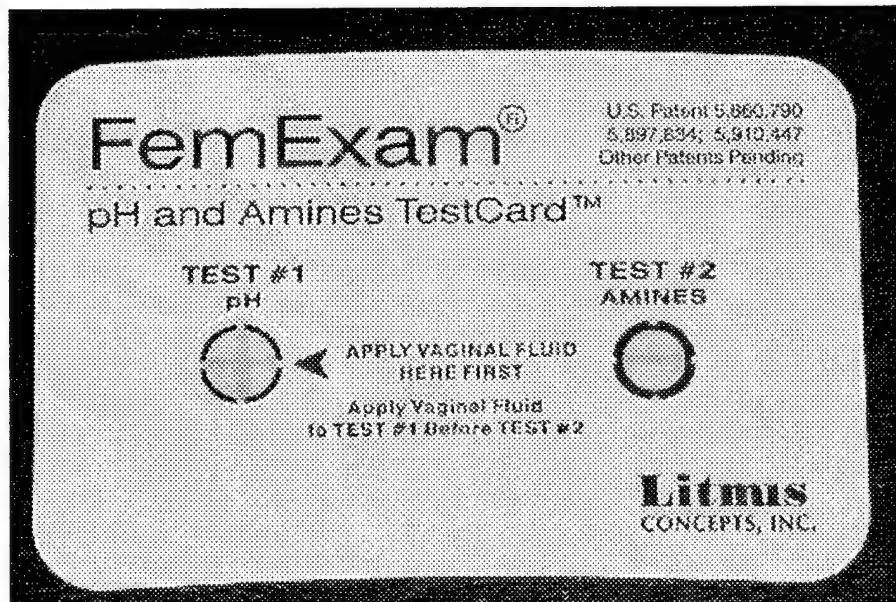
FemExam[®] (bedside)

- 1) Vaginal pH >4.6
- 2) Amines

Microscope



FemExam®



Demographics (n=1944)

Age - yr mean = 19.0 (range 17-33)

Race/ethnicity

Caucasian	56%
Hispanic/Latina	20%
African-American	16%
Asian/Pacific Islander	3%
Native American	2%
Other/mixed	2%

Clinical Characteristics

Sexually experienced	86%
Self-report vag d/c	19%
Self-report vag odor	7%
Clinician detected vag d/c	5%
<i>C. trachomatis</i> (+)	10%
<i>N. gonorrhoeae</i> (+)	2%
<i>T. vaginalis</i> (+)	1%

BV Prevalence

All participants	27%
Sexually experience	28%
Not sexually experienced	18%
Self-report vag d/c	
Yes	33%
No	25%

$p < .001$

Performance of FemExam®

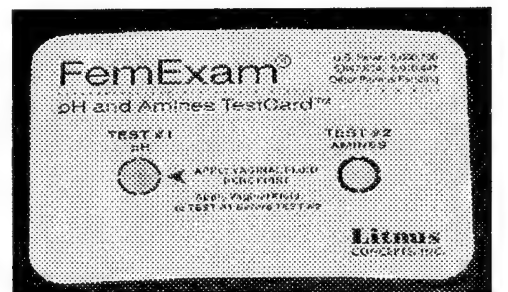
	<u>Sens (%)</u>	<u>Spec (%)</u>
pH and amines	9	99
pH or amines	73	66
pH	72	67
amines	11	97

Performance of Pap Smear

	<u>Sens (%)</u>	<u>Spec (%)</u>
Pap smear	72	79
pH or amines	73	66
pH	72	67

Limitations

- False negatives on amines portion of FemExam® could have resulted from the transient nature of positives due to the volatility of amines.



Prevalence Summary

- 27% in diverse, non-clinic, young women
- Higher in sexually experienced and those who report vaginal discharge

Performance Summary

- FemExam[®] pH → acceptable
- FemExam[®] amines → poor
- Pap smear → similar to pH

Implications

- Mass screening possible for BV using Nugent's criteria or Pap smear
- More reliable rapid "bedside" tests needed
- Research needs to clearly define the relationships between a lab diagnosis of BV (e.g., Nugent's), a clinical diagnosis and true gyn morbidity

Appendix 3c.

Boyer CB, Shafer MA: Development of a cognitive-behavioral group randomized control intervention trial to prevent STDs and unplanned pregnancies for young women entering the US military. Annual meeting of the Society for Adolescent Medicine, Boston MA, March 2002.

DEVELOPMENT OF A COGNITIVE- BEHAVIORAL GROUP RANDOMIZED CONTROL INTERVENTION TRIAL TO PREVENT STDS AND UNPLANNED PREGANCIES FOR YOUNG WOMEN ENTERING THE U.S. MILITARY

Cherrie B. Boyer, PhD and Mary-Ann Shafer, MD
University of California, San Francisco
Department of Pediatrics
Division of Adolescent Medicine

FOCUS

**...on the choices you make now
that will effect your future and career**



Background and Significance

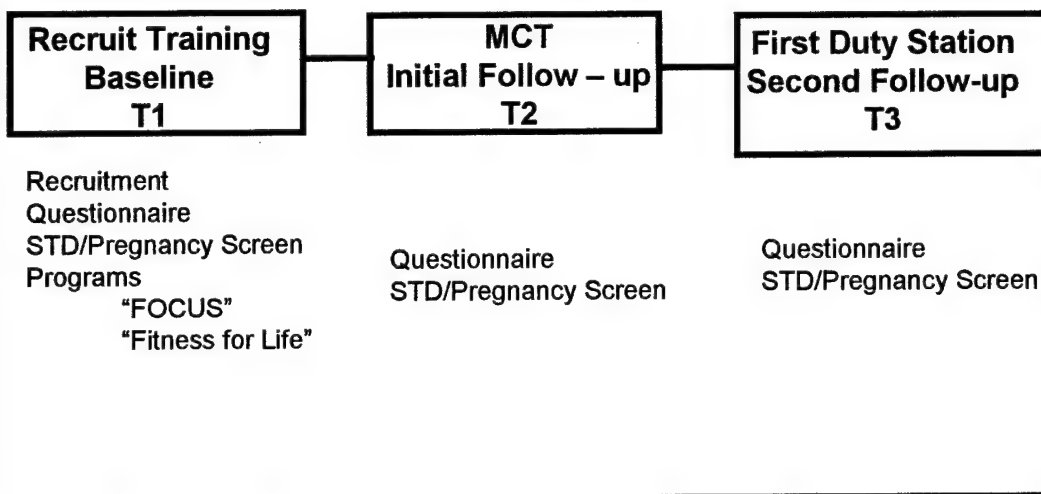
- Sexually experienced women, ages 15-24 years, have higher rates of *C. trachomatis* and *N. gonorrhoeae* than any other age group.
- These infections pose serious health concerns for young women because of their association with adverse reproductive health outcomes such as pelvic inflammatory disease, tubal infertility, ectopic pregnancy, and increased risk of exposure to HIV.
- The risk of exposure to STDs is the result of complex interrelationships among sociodemographic risk markers and behavioral risk factors.
- Much of what is known about these factors is reported from STD and family planning clinics. Such groups may overestimate the prevalence of STDs in young women.
- Women entering recruit training for military service represents a more ideal national, non-clinical cross-section to assess the prevalence of STDs in young women.

Program Objective

To evaluate the feasibility and effectiveness of a cognitive-behavioral intervention to prevent and reduce the risk of HIV/STDs and unplanned pregnancies (UIPs) in young women from throughout the United States entering recruit training for the military.



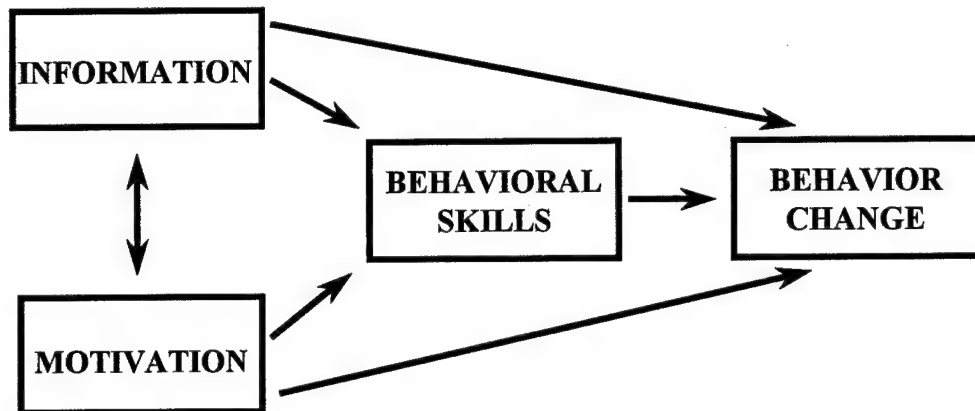
Study Design



Program Overview

- **Approach**
 - Information
 - Cognitive-Behavioral Processes
 - Skills-Building Techniques
- **Strategies**
 - Didactic Slides
 - Interactive Group Exercises
 - Military-Specific Videos
- **Format (Small Groups)**
 - 4, Two-hour Sessions

IMB MODEL



Fisher and Fisher, 1992; 1996

EXPERIMENTAL INTERVENTION

“FOCUS” CURRICULUM GOALS

- Educate participants about the risk and impact of unplanned pregnancies, STDs and HIV.
- Provide participants with factual information about effective methods of contraception and STD outcomes.
- Familiarize participants with the basics of a GYN exam and the female reproductive anatomy.

“FOCUS” CURRICULUM GOALS

- **Develop participants’ communication and decision-making skills regarding sexual behaviors and use of contraception.**
- **Provide participants with information about the effects of alcohol use.**



“FOCUS”

Examples of Didactic Slides

Risk for Unplanned Pregnancy and STDs

- Low self-esteem
- Media influences
- Alcohol and drug use
- Lack of information
- Lack of access to care
- Difficulty in negotiating with partner
- Other

Consequences of Unplanned Pregnancies

- Emotional-psychological
- Interruption of career
- Financial

Contraception Considerations

- Availability
- Effectiveness
- Protection against STDs
- Ease of use
- Safety
- Cost
- Control
- Reversibility
- Values and beliefs
- Control over use

“FOCUS”

Examples of Didactic Slides

Consequences of STDs in Women

- Passed to babies during pregnancy/birth
- Tubal blockage — infertility — ectopic pregnancy
- Cervical Cancer
- Increased vulnerability to HIV/AIDS

STDs/HIV are Prevented By:

- Abstinence
- Safe Sex
- Monogamy
- Honesty with partner about past sex
- Screening tests for STDs
- Not using unsterile needles

Blood Alcohol Effects

- .02% Feel some effects, driving skills impaired
- .04% Begin to feel relaxed
- .06% Judgment is impaired
- .08% Problem with coordination, driving skills, nausea, slurred speech
- .10% Reaction time dramatically reduced
- .15% Balance and movement impaired, risk of blackouts and accidents dramatically increased
- .30% Most people lose consciousness
- .35% CNS is substantially depressed, risk of death

“FOCUS”

Example of a Role-play Exercise

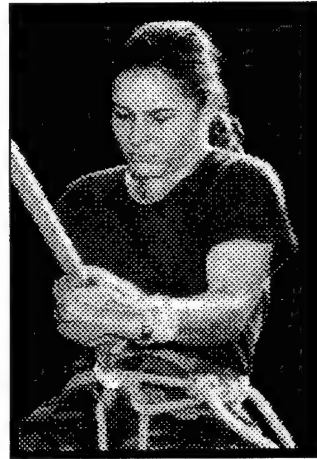
“Let’s talk about sex and contraception”

“Imagine that you are in the beginning weeks of a new relationship. You really like this guy a lot and think this relationship has the potential to develop into something special. But you want it to be different than previous relationships. You’ve promised yourself that in any new relationship you will start off by being open and honest in talking about sex before you’re in the heat of the moment. You also realize that beginning the conversation is difficult and a little scary. What do you say?”

CONTROL INTERVENTION

“FITNESS FOR LIFE” CURRICULUM GOALS

- **Improve participants' physical performance through healthier food choices.**
- **Reduce participants' risk of sports/physical training injuries.**
- **Examine the risk and prevention of cervical and breast cancer.**



Methods

- **All women recruits between June 1999 and June 2000 were approached to participate in the study.**
- **95% of women voluntarily agreed to participate either in the cognitive-behavioral, skills-building intervention (FOCUS) to prevent unplanned pregnancies and STDs or a nutrition and fitness program (Fitness for Life). Assignments to the programs were random.**
- **The participants completed a self-administered questionnaire and were screened for asymptomatic *C. trachomatis*, *N. gonorrhoeae*, *T. Vaginalis* and pregnancy at baseline, and two follow-up periods.**

SELF-REPORTED QUESTIONNAIRE

Sociodemographic Risk Markers

- Age
- Race/Ethnicity
- Marital Status
- Education
- Geographic Residence
- Sexual partner's age
- Sexual partner's race/ethnicity

SELF-REPORTED QUESTIONNAIRE

Behavioral Risk Factors

- Age at sexual debut
- Number of sexual partners
- Number of casual partners
- Frequency of birth control
- Frequency of condom use
- Frequency of alcohol and substance use
- Frequency of sex under the influence of alcohol and substance use
- Frequency of contraception use at last sex
- Perception that sex partners had a history of STDs
- Perception that sex partners had other partners

SELF-REPORTED QUESTIONNAIRE

Clinical Risk Factors

- History of pregnancy
- History of STDs
- Vaginal symptoms at screening

STD Screening

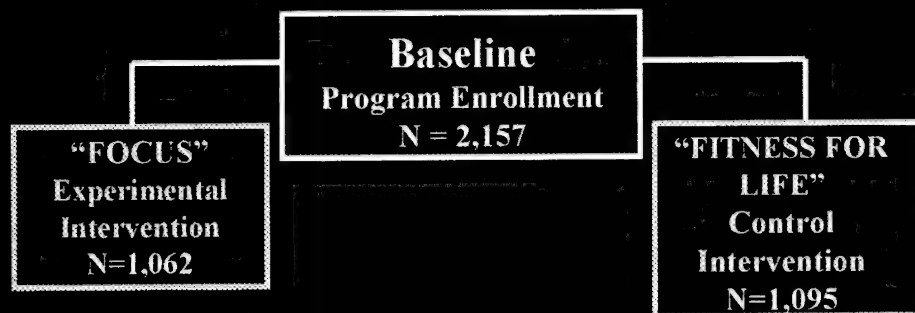
C. trachomatis* and *N. gonorrhoeae

Participants provided 20-25 ml of first catch urine (FCU) and self-administered vaginal swabs for LCx tm processing (Abbott Laboratories).

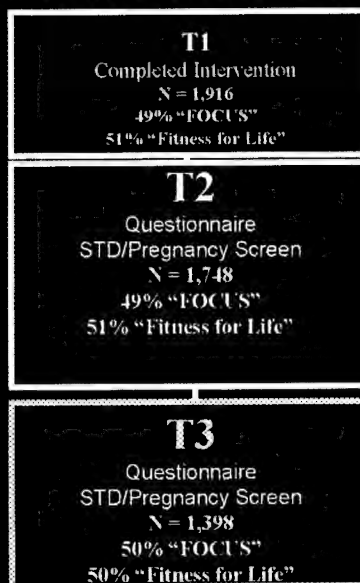
T. vaginalis

A self-administered vaginal swab was processed using In-Pouch TV tm (Biomed Laboratories).

Group Assignment



Intervention & Follow-up



Baseline Results

Sociodemographic Markers

Age

17-18	52%
19-20	32%
≥ 21	16%

Race/Ethnicity

Caucasian	57%
Latina	20%
African American	17%
Asian/PI/Native American	6%

Sociodemographic Markers

Marital Status

Single	92%
Married	8%

Level of Education

High School Diploma/GED	73%
College/Vocational School	27%

Geographic Residence

Urban	78%
Rural	22%

Years of sexual experience

≤1	26%
≥2	74%

Sociodemographic Markers

Age of Last Sexual Partner

≤ 20	49%
21-23	25%
≥ 24	26%

Sexual Partner's Race/Ethnicity

Caucasian	58%
Latino	19%
African American	19%
Asian/PI/Native American	4%

Behavioral Risk Factors (Lifetime)

Sexual Partners

1	18%
> 2	82%

Casual Partners

1-2	34%
>3	66%

Frequency of Birth Control

Never/Almost Never	20%
Sometimes	13%
Usually/Always	67%

Condom Use

< 100%	78%
100%	22%

Behavioral Risk Factors (Prior 3-months)

Sexual Partners

1	88%
≥ 2	12%

Casual Partners

0-1	89%
≥2	11%

Frequency of Birth Control

Never/Almost Never	30%
Sometimes	9%
Usually/Always	61%

Condom Use

Never	26%
< Always	47%
Always	27%

Behavioral Risk Factors (Prior 3-months)

Heavy Drinking

Yes	14%
No	86%

Substance Use

Yes	6%
No	94%

Sex Under the Influence of Alcohol/Substances

Never	43%
Almost Never/Sometimes	46%
Usually/Always	11%

Behavioral Risk Factors (Prior 3-months)

Sexual Partner's Risk

Perception of STD history	25%
Perception of other partners	18%
Do not perceived partner to be at risk	57%

Clinical Risk Factors

History of Pregnancy	16%
History of STDs	11%
Vaginal Symptoms at Screening	24%

STDs at Screening

STD positive	13%
CT	11%
GC	2%
TV	2%
Multiple diagnoses	1%

T2 CLINICAL RESULTS

Marine Combat Training

STD POSITIVE	4.0 %
Focus	20 (4 %)
Fitness	31 (6 %)
 POSITIVE PREGNANCY	 0.4 %
Focus	4 (0.8 %)
Fitness	4 (0.8 %)

T3 Results To Date

- We have followed 1,398 women at T3 (9-11 months post intervention). This represents 73% of the 1,916 women who completed the intervention.
- Of the women followed at T3, 50% were assigned to the experimental condition and 50% were assigned to the control condition.
- 10% of the women who completed the intervention declined further participation in the program and 13% were been lost to follow-up (largely due to being discharged from the military).

Implications

- Although it is too soon to evaluate the effectiveness of the intervention, we have demonstrated that an intervention such as this is feasible in this field setting.
- Our baseline findings of a high prevalence of sexual risk factors and STDs in this national, non-clinical sample of young women suggest the need for ongoing comprehensive interventions for young women post high school.

Implications

- Such interventions should integrate STDs, HIV, and UIP prevention into a single program and include STD screening and cognitive-behavioral risk reduction strategies